REMARKS/ARGUMENTS

Claim 1 is active in this case. Claim 1 has been amended for clarity. Support for the amendment is found in the specification on page 5, 2nd paragraph and the paragraph bridging pages 10-11.

No new matter is believed to have been added by these amendments.

The rejection under 112, second paragraph based on the usage of the term "genotypes" is no longer applicable in light of the amendment. As is understood from reading the specification, determining the genotype at the DRB1* locus for the table used to compare with antibody titers is a measure of homozygosity/heterozygosity of the DRB*1 allele. Indeed, as the Examiner already noted, the terms of allele and genotype are well known in the field of genomics as are the terms homozygous and heterozygous in diploid organisms.

Withdrawal of the rejection is requested.

The Examiner continues to maintain that the claimed method is not enabled. In particular, as outlined in the Action beginning on page 4 the Examiner focuses on the alleged unpredictability in the art based on other publications (Acton, Ozawa and others) in which a correlation between DRB1 and caries is not readily attainable. The Examiner also again alleges that the specification does not identify any DRB-1 carries or relationship of statistical significance. In addition, the Examiner again refers to the table in the Declaration as evidence of the unpredictability of the claimed method.

Applicants disagree and request reconsideration in light of the amendments submitted and the following remarks.

As discussed on page 5, one element of caries risk is the assessment of initial adhesion of mutans streptococci to the tooth surface where the method claimed assessing antibody titer to SEQ ID NO:1 as a measure of that adhesion. Then correlating the levels of mutants streptococci to the risk of developing caries. That is, it is assessing relative risks not an absolute test as to whether the individual being tested is actually suffering from caries, the method aims to assess the adhesion of mutans streptococci as a risk factor or probability for caries.

This is shown by the data of record.

This method provides are more accurate testing method thereby having great value in the field of dental medicine. Moreover, this method has particular advantages for assessing caries risk in infants, less than about 6 years of age, due to their incomplete immune system and for which traditional immunological methods would not sufficiently detect the caries risk (see page 5, last paragraph of the specification).

The invention (and claim 1 as presented) requires that a table be prepared before the method. This table correlates homozygous or heterozygous (genotypes at the DRB*1 and the relationship of an antibody titer of a secretory IgA in human saliva against an antigen (defined by SEQ ID NO:2 in claim 1). So then, what one has to do is compare homozygosity/heterozygosity of the DRB*1 allele to antibody titer. The antibody titer is a measure of mutans streptococci on the tooth surface. The level of mutans streptococci on the tooth surface an indicator of probability or risk in caries.

For example as shown in the table in the previously submitted Rule 132 Declaration, when a patient is heterozygous at DRB1* and only one allele had been identified before (e.g., DRB1* 0803), the caries risk (that is the level of adhesion of mutans streptococci which can then be correlative to a probability of caries) of the patient could not be determined because if another allele was DRB1*0410, the caries risk (based on the antibody titer, which in turn, is

based on antibody/antigen interactions) was low, and if it was DRB*1 1202, the caries risk is high. After determining what combination the patient had, in terms of genotypes, the caries risk can be determined by comparing that genotype to the table.

Certainly, it can be recognized that assessing an antibody titer to a pathogen adhered to the tooth surface is doable without undue experimentation using routine and well-known antibody-antigen testing. Having this information in hand, one can then assess the probability or risk of caries in the patient based on an alignment of the genotypes associated with certain antibody titers or levels.

Genotyping is a procedure that is common and well-used in the field.

Determining antibody titer is common and well-used in the field.

Therefore, as the tools for performing the method, generating the table (prepared beforehand) and making the requisite comparisons is within the skill in this field, it is respectfully submitted that it would not require undue experimentation for such a person to carry out the claimed method based on what is described in the specification as originally filed.

Applicants also request a Notice of Allowance.

Respectfully submitted,

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